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13. SUPPLEMENTARY NOTES			
14. ABSTRACT			
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WellDoc, Inc., 1501 St. Paul Street, Suite 118 Baltimore, MD 21202

#### Final Report

Mobile Diabetes Management for USAF Active and Retired Military Spouses

### September 24, 2013

Reporting Period: 28 Sept 2010-30 Sep 2013

Prepared for
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Under Contract Number

FA7014-10-C-0031

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DISTRIBUTION STATEMENT

Distribution A

UNCLASSIFIED



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## Section II - Executive Summary

This report concludes the Mobile Diabetes Management for USAF Active and Retired Military Spouses (MDM) project, which was directed at examining the use of technologies that patients and healthcare providers use in their everyday lives and practices to support optimized diabetes clinical outcomes and self-management support.

WellDoc(WD) submitted Proposal No. 1000-01 in response to the Air Force BAA 09-01 with the original intent to support the integration of this mobile technology – to enhance and expand both civilian and military diabetes care – in the context of military electronic medical records (EMRs), namely AHLTA. WellDoc was authorized to conduct the project with a non-military clinical organization and a commercial EMR vendor. WellDoc subcontracted with The George Washington University Medical Faculty Associates, (GWMFA), and a well-known clinical organization that had broad experience with implementing a customized version of the Allscripts Electronic Medical Record (EMR). The project was initially envisioned to accomplish three objectives (which are detailed in subsequent sections) that are summarized below:

- 1. Task 1 WellDoc DiabetesManager® / GWMFA Allscripts Enterprise EHR Integration
- 2. Task 2 IDM® Human Factors and Usability Pilot
- 3. Task 3 Conduct the Mobile Diabetes Management Clinical Trial

The first objective has been successfully addressed and a whitepaper capturing the lessons learned during the technical integration phase of the project has been published in a peer-reviewed journal.<sup>1</sup> However, due to unforeseen technical,

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<sup>&</sup>lt;sup>1</sup> Peeples, M., Iyer, A., Cohen, J. Integration of a Mobile Integrated Therapy (MIT) with Electronic Health Records: Lessons Learned. Journal of Diabetes Science & Technology. May 2013, Volume 7, Issue 3: pages 602-611.



workflow and clinical issues in this first-of-a-kind integration, Task 1 took much longer than anticipated; while the learnings proved significant, insufficient time was left to address Task 2 and Task 3 project objectives. Other studies have been conducted in parallel with this project effort that have demonstrated both usability and clinical outcomes of the mobile technology solution and therefore while not completed under this contract, the broader academic objectives for learning have been addressed with adjunct efforts.<sup>2</sup>

Therefore, the project concluded after the successful completion of the first objective and partial completion of the remaining two objectives. The remainder of this document addresses the following:

- Context
- Project Objectives and Statement of Work
- Progress Against Contract Tasks, Deliverables and Milestones
- **Project Summary**
- Recommended Next Steps
- **Appendices** 
  - A. Broader Lessons Learned Whitepaper
  - B. Peer-reviewed Technical Journal Article
  - C. Program Review Presentation with AF on April 18, 2013
  - D. Draft of Recommended Next Steps

<sup>&</sup>lt;sup>2</sup> Quinn CC, Shardell MD, Terrin, ML, Barr EA, Ballew SH, Gruber-Baldini AL. A cluster randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011, Sep; 34:1934-42.



## Section III - Background

There are currently 24 million people in the United States (U.S.) with diabetes and that number is increasing annually at a rate of one million newly diagnosed patients with diabetes per year<sup>3</sup>. This growth is causing a tremendous public health burden. Even though the military tends to have a younger and more physically active population than US population as a whole, the military healthcare system is experiencing a similar burden from the increasing prevalence of diabetes. Using recently published data we calculated that the annual expenditure by the Department of Defense for active, retired, and beneficiary military with type 2 diabetes is \$465,722,460. This reflected some 42,536 hospitalizations at a \$2281 per day costs<sup>4</sup>. This compares with national data from the American Diabetes Association, for diabetes emergency room (ER) visits and hospitalizations were estimated to cost \$696 per ER visit and \$1,853 per day of hospitalization.<sup>5</sup> In addition to the increasing costs, patient outcomes for diabetes management are getting worse. Whether military or civilian, the current patient-provider treatment paradigm for diabetes does not allow for the frequent, personalized, and data-driven interventions required to support effective diabetes medical treatment and patient self-management. In addition to the increasing costs, patient outcomes for diabetes

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<sup>&</sup>lt;sup>3</sup> CDC. National Center for Chronic Disease Prevention and Health Promotion. 2007 National diabetes fact sheet; 2008 Available from: http://www.cdc.gov/diabetes/pubs/estimates07.htm#. 2009

<sup>&</sup>lt;sup>4</sup> Lott, *A Genomics Study of Type 2 Diabetes Mellitus in US Air Force Personnel*, Journal of Diabetes Science and Technology, July 2009.

DoD Active Duty Military Personnel by Rank/Grade, 2013, www.kb.defense.gov

Hospitalizations for Diabetes as Any-Listed Diagnosis per 1000 Diabetic Population, United States, 1988-2009, www.cdc.gov

Average Length of Stay (ALOS) in Days of Hospital Discharges with Diabetes as Any-Listed Diagnosis, United States, 1988-2009, www.cdc.gov

Facts and Figures, Diabetes in the United States, Congressional Diabetes Caucus (data from American Diabetes Association (ADA), www.house.gov

<sup>&</sup>lt;sup>5</sup> American Diabetes Association. Economic costs of diabetes in the U.S. In 2007. Diabetes Care 2008 Mar;31 (3):596-615.



management are getting worse. Even with all the diabetes therapies and devices, the current diabetes treatment does not allow for the frequent, personalized, and data-driven interventions required to support effective diabetes medical treatment and patient self-management. Based on technology developed by WellDoc, Inc (WellDoc), WellDoc proposes to work with industry leading software developers and academic partners to demonstrate the effectiveness of a mobile diabetes management system integrated with an electronic health record (EHR) to support diabetes patients and their providers.



# Section IV - Project Objectives and Statement of Work

The project's objective was to assimilate electronic health record (EHR) data with patient-entered self-management and behavioral data into a data analysis report for clinicians, which includes treatment recommendations generated by disease specific, evidence-based guidelines (EBG) used in conjunction with real-time patient selfmanagement tools, with the aim of improving diabetes outcomes demonstrating the potential to impact healthcare in alignment with the AFMS/DoD treatment paradigm<sup>6</sup>.

The specific tasks and associated aims of this study were:

#### Task 1 – WellDoc DiabetesManager® / GWMFA Allscripts Enterprise EHR Integration

Integrate the WellDoc DiabetesManager® system with GWMFA's Allscripts Enterprise EHR to create the WellDoc Integrated DiabetesManager® to provide "mobile diabetes management" for patients and enhanced data for providers. This will require a technical integration of the mobile and webbased components of the WellDoc DiabetesManager® with GWMFA's Allscripts Enterprise EHR system and setup the system for use by patients and providers.

#### Task 2 - IDM® Human Factors and Usability Pilot

The task requires analysis to determine the usability of IDM® by clinicians and patients using the IDM® solution. A human factors and usability study will be conducted using a representative sample of healthcare providers and patients at GWMFA to demonstrate there are no user related hazards and determine any software design changes needed.

#### Task 3 - Conduct the Mobile Diabetes Management Clinical Trial

Conduct the Mobile Diabetes Management Clinical Trial at the MFA with patients and providers to evaluate clinical outcomes, cost-effectiveness, and technical integration. "Mobile diabetes management" will be implemented at the MFA for patients with diabetes. WellDoc and MFA will partner to conduct a 12-month clinical study to determine the impact on patient outcomes and diabetes disease management.

<sup>&</sup>lt;sup>6</sup> AFMS/DoD Treatment Paradigm accessed at https://www.qmo.amedd.army.mil/diabetes/diabfr.htm. 2009



## Section V - Project Summary

On April 18, 2013 WellDoc delivered a comprehensive presentation on the Mobile Diabetes Management project<sup>7</sup>, including the integration of WellDoc's DiabetesConsort product into GWU's Allscripts Enterprise EMR, to the broader Air Force project team, Air Force Medical Support Agency leadership, and interested military stakeholders. The WellDoc and GWU MFA team presented the working product, demonstrating the completion of the technical portion of the initially envisaged integration project. At a high-level, during the project's period of performance, WellDoc and GWU MFA accomplished the following:

#### **Task 0: Project Management**

- Successfully kicked off project with a cross-functional team from AF, WellDoc and GW's MFA
- Developed and tracked a comprehensive Project Plan for all tasks and deliverables in Microsoft (MS) Project
- Delivered a draft final report (this document)
- Delivered final report (to be delivered with an initial review of the draft)
- Delivered monthly project reports (which can be furnished upon request)
- Participated in monthly project review teleconferences

### **Task 1: Technical Integration**

- Completed a Functional Requirements Document (FRD)
- Completed a High-level System Description Document (SD)
- Created and documented a Technical Architecture Alternative Summary Document
- Defined a set of reporting metrics to track progress
- Completed a technical Functional Specification Document (FSD)
- Completed an Integrated Module Design (IMD) Document

<sup>&</sup>lt;sup>7</sup> See Appendix C



- Developed a comprehensive set of Use and Test Cases
- Developed a Concurrent Test Case Design Document
- Completed multiple development reviews to ensure technical integrity of the solution
- Delivered HTML screen shots for the integrated product views
- Delivered internal testing results through a Pass/Fail Report
- Conducted and documented results from External Field Tests
- Conducted and documented results from User Acceptance Tests
- Reviewed and documented a Clinical Assessment of the Technical Integration (Task 1)

### Task 2: Human Factors and Usability Pilot

- Created and finalized Clinical Protocol (CP)
- Finalized and submitted CP to IRB
- Documented UAT and EFT results
- Completed Clinical Review (CR) and sign off for Patient and Provider Use
- Note: The project did not complete the HF and Usability Pilot due to insufficient time for recruitment and following patients to obtain statistically relevant data and findings

#### **Task 3: Conduct Clinical Trial**

- Obtained IRB Approval from both GWU and AF IRBs
- Note: The project did not complete the Clinical Trial due to insufficient time for recruitment and following patients through a sufficient enough (e.g., 9-12 month) period to observe longitudinal patient health outcomes improvements

The collective above progress points represents substantial completion of Tasks 0, 1, and the regulatory requirements for Task 2. Due to the extended time required to complete the aforementioned tasks, it was determined that the time remaining on the contract performance period was insufficient for the completion of the Pilot (Task 2) and Task 3.



## Section VI - Recommended Next Steps

WellDoc recommends the Air Force continue its significant strides forward in Mobile Integrated Therapy through the integration of BlueStar<sup>8</sup> into AHLTA. The value proposition: help deploy a commercial-grade, Rx version of the mobile diabetes solution into AHLTA to improve healthcare outcomes and reduce healthcare costs. Why? Earlier versions of the mobile technology that is BlueStar have demonstrated a ~2-point reduction in HbA1c in type 2 diabetes patients in randomized control studies, as well as a 58% reduction in ER visits, and 100% reduction in hospital admits in studies with GWU. The cost implications of the above two points are a savings of \$390 to \$630 per patient per month. Other benefits would include access to BlueStar patient and population data (and SmartVisit patient report and summaries) within AHLTA, alignment with HEDIS and Meaningful Use (Stages 1-3) legislation, and finally, alignment to ACO/PCMH legislation in the Affordable Care Act. Appendix 4 contains a suggested scope of work as part of our recommended next steps.

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<sup>&</sup>lt;sup>8</sup> BlueStar is the Rx version of the mobile technology that is now reimbursed and being launched with payors



## **Appendix**

Appendix A: Lessons Learned White Paper

Appendix B: Journal Publication on Lessons Learned

Appendix C: April 18, 2013 WellDoc Presentation to Air

Force on Project Status

Appendix D: June 25, 2013 WellDoc Presentation for Next

Steps



## Appendix A: Lessons Learned White Paper



# Lessons Learned in the Integration of Mobile Integrated Therapies (MIT) into Electronic Medical Records (EMR)

A white paper submitted to the Headquarters United States Air Force Surgeon General (HQ AF/SG)

Contract No. FA7014-10-C.0031

**Authored By:** 

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# Foreword and Acknowledgements

This white paper introduces a new category of therapy that has evolved with the ubiquitous acceptance of cellphone and Internet technology. Mobile integrated therapy, or MIT, is a solution that holistically engages patients in the self-management of their disease. MIT decentralizes the delivery of healthcare and empowers patients and providers through the use of wireless mobile devices and the Internet. At its heart, MIT represents the convergence of mobile technology, clinical, and behavioral science and validated clinical outcomes, to create a new-to-the-world health care solution that supports patients in all aspects of their care.

In this paper we will highlight key "lessons learned" from the technical integration of a patient-centered, mobile diabetes management solution into the electronic medical record (EMR) of a multi-physician practice within a large, urban academic medical center. Using diabetes as the surrogate disease for integrating patient self-management data with medical record data provides the opportunity to understand the bi-directional data sharing and reporting that is most valuable in advancing better health and better care in a cost-effective and scalable manner for all chronic diseases.

We would like to take this opportunity to place on record our appreciation of the funding and leadership contributions of the United States Air Force on the project. Specific mention goes to Lt. Col Mark True and Lt. Col Cherri Shireman, whose interest and passion for innovation go well beyond the norm. We also recognize the contributions of Sandra Bailey, Velda Johnson and Marybeth Peters in supporting the project management and reporting aspects of the effort. This project was jointly conducted with The George Washington University Medical Faculty Associates (MFA). We recognize and thank Dr. Joshua Cohen and the members of his staff for their insights and leadership. We also thank Praveen Toteja, Chief Technology Officer, GW MFA and the IT Department for their assistance during the



technical phase of integration into GW's electronic health record. Finally, we recognize the contributions of the EHRI consultants who assisted in the technical integration – Anthony Nuzzo and Matt Greenwald.

We are confident that these lessons learned will help accelerate the integration of mobile integrated therapies into electronic medical records, which will ultimately improve the quality and costs associated with managing chronic diseases in the U.S. The societal and economic potential of such solutions – for patients, providers, and for the U.S. as a whole – is staggering. We appreciate the opportunity to be innovators in this transformative initiative to make a positive impact upon healthcare outcomes and costs, and in the lives of people who suffer from chronic conditions.

Dr. Anand K. Iyer

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## Chronic Diseases: Why MIT and EMR Integration?

Chronic Disease management is a challenge not only for the person with the disease, but for the health care providers who are developing and guiding the treatment plan, and also the health care system and payers who provide the infrastructure for the care delivery. Further, the number of people with multiple chronic diseases, not just a single chronic disease, has mushroomed to new levels in the last decade.

In 2012, spending on chronic diseases in the United States represents 75% of the \$2 trillion devoted to health care, and such diseases are responsible for 7 out of 10 deaths annually<sup>9</sup>. Nearly 86 million Americans today have not had any healthcare insurance coverage during the last two years; millions more lack full healthcare coverage<sup>10</sup>. The pharmaceutical industry laments the current state of medication adherence, which for many drug classes, quickly drops to below 30% in a matter of two to three refill periods for a given drug. And disease management, the "high-attention" call-center based services, are tapping into every avenue available to determine how to raise engagement rates from levels that currently sit below 5%<sup>11</sup>.

Unfortunately, our traditional health care infrastructure and workforce numbers have not grown rapidly enough to accommodate our chronic disease patients. One can argue that chronic disease management, which has a large self-management component, should not be managed with traditional approaches. In fact, during the last decade, standardized approaches to chronic disease management using tools

<sup>&</sup>lt;sup>9</sup> http://www.healthcare.gov/news/factsheets/2011/05/grants05132011a.html. Accessed 11/09/2012.

<sup>&</sup>lt;sup>10</sup> CNN, 2010 ; 2009 US Census Bureau. Accessed 11/09/2012.

<sup>&</sup>lt;sup>11</sup> McCall N, Cromwell J. Results of the Medicare Health Support disease-management pilot program. N Engl J Med. 2011 Nov 3; 365(18):1704-12.



such as the Chronic Care Model<sup>12</sup> have been rapidly evolving, and along with that an increasing attention to and measurement for the patient role in the approaches to chronic care has evolved as well.

That being said, there remain real barriers to managing chronic diseases that must be taken into consideration:

- Chronic disease management is incredibly burdensome for patients. Management of many chronic diseases places undue burden upon patients to log significant amounts of multi-variate data (e.g., medication use, physical/psychological symptoms, episodic testing, activity, nutrition, etc.) asynchronously throughout any given day, and to recall the correct (and often complex) medication and/or treatment instructions. It is, simply put, like learning a foreign language and thus often gets de-prioritized in the course of daily life.
- Patients have limited support outside of the clinical setting. Our healthcare system, and for that matter, most throughout the world, were designed to support acute care; they don't effectively support the needs of chronic disease management, especially at the exploding incidence rate of chronic disease we have in the United States (and throughout the world). Studies have shown that patients who have difficulty recalling physician instructions as much as 50% of the time<sup>13</sup>. In a dynamic world, patients need dynamic access to relevant and timely education outside of their healthcare provider's office.
- Healthcare providers don't get the data they need. Dependent on patient daily and/or weekly metabolic self-monitoring activities such as blood glucose

<sup>&</sup>lt;sup>12</sup> Wagner, E.H. Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? Effective Clinical Practice 1998; 1:2-4.

<sup>&</sup>lt;sup>13</sup> Schillinger D, Piette J, Grumbach K, Wang F, Wilson C, Daher C, Leong-Grotz K, Castro C, Bindman AB Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med. 2003 Jan 13; 163(1):83-90



or blood pressure measurment, healthcare providers often have limited, incomplete, and/or inaccurate information to use as a basis for treatment or to make medication modifications.

- Office visits are too short and too infrequent. Typically, physicians have 15 minutes or less during a patient office visit to review charts, examine patients, analyze data, and develop a report. Typical patients may only see their physicians two or three times a year; thus, patients do not receive the levels of support and feedback essential for them to effectively sustain their chronic disease management efforts.
- Primary care physicians aren't always aware of the latest evidence-based guidelines. As the gatekeepers to our healthcare system, primary care doctors see and treat the overwhelming majority of patients in the United States. In the current clinical paradigm, it is unrealistic to expect primary care physicians to know and treat to the latest Evidence Based Guidelines for all chronic diseases. To accomplish this, they need technological support that fits within their practices and processes.

The role of patient self-management in chronic disease outcomes has been clearly established during the last decade, yet the inclusion of this activity in quality reporting has not occurred. This omission is due primarily to the lack of well-defined and tested measures, the inherent challenges of self-reported data, and the technological ability to capture this data. Remote monitoring devices (e.g., blood pressure cuffs, weight scales, and even blood glucose meters) have provided initial movement into this area, yet these devices have only served primarily as data transfer devices so that data from a home setting can be displayed in an electronic medical record for review, analysis, and decision-making by the providers. Incrementally, blood glucose meters have transitioned from data collection devices to having the ability to download the output to a graphical report that can be scanned into an electronic medical record. Currently lacking with the remote monitoring, however, is insight into daily activities that can be obtained through patient self-reported data.



At the same time, we know that simply transmitting raw data from patients to physicians does not generate a positive return on investment (ROI) in the form of health or economic outcomes<sup>14</sup>. To date, the health and economic outcomes of effective management of chronic diseases have traditionally been driven and measured from the perspective of the health care system providers, as this was where the data was available for collection, aggregation, and reporting. Initially, claims and administrative information provided the bulk of the data for reporting, and this informed the initial development of national metrics such as Healthcare Effectiveness and Data Information Set (HEDIS) and the National Committee for Quality Assurance (NCQA) quality measures. With the introduction of electronic medical records, electronic laboratory reporting, and e-prescribing, the focus of these measures became more specific. For example, the diabetes care metric for glucose control has evolved from the percentage of the population having the A1c test done within a given time frame, to the percentage of the population having an A1c value greater or less than 9%<sup>15</sup>.

Predictably, the chief challenges to prompt and effective outcome reporting have been primarily related to the manual and paper-based nature of medical records. With the introduction of EMRs, the expectation was that this reporting would rapidly change. However, as is well known today, health care providers are generally slow to adopt the use of EMRs for a variety of reasons, and among those were the cost and need to change their practice and workflow models. In 2009, the *Health Information Technology for Economic and Clinical Health Act*<sup>16</sup> (HITECH Act) incentivized electronic record adoption and promoted meaningful use of the

<sup>&</sup>lt;sup>14</sup> McCall N, Cromwell J., Results of the Medicare Health Support disease-management pilot program.
N Engl J Med. 2011 Nov 3;365(18):1704-12

<sup>&</sup>lt;sup>15</sup> Cebul RD, Love TE, Jain AK, Hebert CJ. Electronic health records and quality of diabetes care. N Engl J Med. 2011 Sep 1;365(9):825-3

http://www.healthit.gov/policy-researchers-implementers/health-it-rules-regulations. Accessed 11/9/2012



records to impact quality of care. The Meaningful Use Rules outline a staged approach to the implementation of interoperable records and increasing specificity of quality metrics and involvement of patient-centric care each stage. Stage 3 of the Meaningful Use Rules incorporates patient self-reported data. As more providers adopt the electronic records and work to integrate quality reporting into their workflows, the expectation is that their ability to achieve national care metrics will be increasingly facilitated.

What is needed now is to transform this raw data into meaningful and medically relevant information for patients – at the right place, at the right time, in the right format, and with the right context. Information alone is insufficient; it must be translated into supported, achievable, and personalized actions for the individual.

Wireless communications help to provide the fabric required to enable actionable information and knowledge transformation. In 2012, cellular penetration in the U.S. crossed 100% of the population for the first time in U.S. history, topping 322M subscribers<sup>17</sup>, an interesting statistic when compared with the 255M passenger vehicles registered in the U.S.<sup>18</sup> Indeed, Americans may have found a new love – their cell phones! Monthly SMS volume has grown from a mere 5.8 billion messages in 2005 to over 2 trillion in 2012<sup>19</sup>. Combining these figures tells us two things: first, there is an opportunity to leverage the cellular platform as a means of providing actionable healthcare information access to those who do not have access to traditional means of care. Second, the U.S. has an unprecedented opportunity to leverage a lower-cost platform to connect patients, providers, and provide actionable care at the point of care, at the right time and in a manner that fits into the day-to-day lives of patients and the clinical workflow of providers. There is an opportunity to address the issues in a smart, novel, and efficient manner.

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<sup>&</sup>lt;sup>17</sup> http://www.ctia.org/advocacy/research/index.cfm/aid/10323 Accessed 11/13/2012

<sup>&</sup>lt;sup>18</sup> http://www.fhwa.dot.gov/policyinformation/pubs/pl0802<u>1/fig3\_1.cfm</u> Accessed 11/13/2012

<sup>&</sup>lt;sup>19</sup> http://www.ctia.org/advocacy/research/index.cfm/aid/10323 Accessed 11/13/2012



During the last five years, with the ubiquitous adoption of mobile technology throughout all population demographics both nationally and internationally, a new platform for data collection and patient-provider communication has developed. The cell phone represents a technology platform that is available to the patient on a 24/7 basis with the capability of providing real-time messaging (alerts, reminders, feedback), geo-location services, and other features, as well as being an ideal data capture device. These technology capabilities have stimulated the development of some 10,000 software applications for all the mobile phone operating systems (i.e., iPhone, Android, etc.). The applications range from health and wellness products to applications that are being specifically used in the management of disease. These applications used in disease management are termed medical devices – and as such require review by the Food and Drug Administration (FDA)<sup>20</sup>.

In this white paper, we highlight our lessons learned from the technical integration and interface of the mobile application, Diabetes Consort™, with the Allscripts Enterprise EMR system being used at The George Washington University Medical Faculty Associates.

Diabetes Consort<sup>™</sup> is a Class II medical device, cleared by the FDA, which provides adults with type 2 diabetes real-time, contextually relevant coaching and education. This automated feedback is tailored to the patient's treatment plan and behavioral readiness to effectively support lifestyle decisions and treatment plan adherence. The product also provides physicians with clinical decision support to help them individualize and optimize treatment guidelines for patients.

This project is funded by the United States Air Force under Contract No. FA7014-10-C.0031. The technical work has been done by EHRI consultants, the GW Information Technology Department, and WellDoc. A clinical study is in progress to evaluate the

<sup>&</sup>lt;sup>20</sup> http://www.fda.gov/medicaldevices/productsandmedicalproce<u>dures/ucm255978.htm</u> Accessed 11/13/2012



impact of the integration of the patient mobile diabetes solution with the provider electronic medical record to measure the impact on health, care, and costs.



### **Project Background**

As depicted in Figure 1, the initial proposal was aimed at integrating WellDoc's MIT solution into AHLTA as sponsored by the Air Force. However, upon further review and examination with the Air Force, due to access restrictions, the Air Force directed WellDoc to execute the integration with a commercial EMR vendor in a commercial care setting.

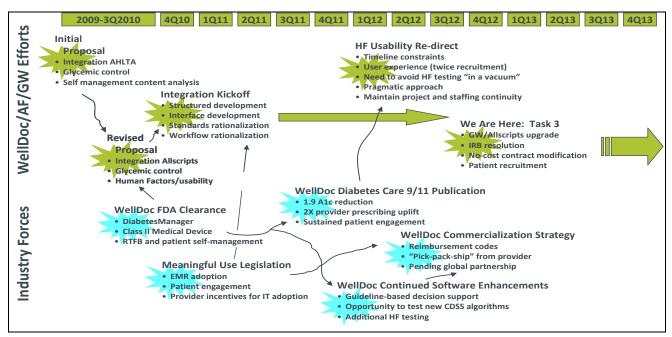


Figure 1. Project Timeline, Work Activities, and Industry Forces.

At the time of project initiation, two landmark events occurred:

- WellDoc was granted a 510K Class II clearance from the FDA for its MIT solution. An industry first, the granting of such a clearance had many constraints that came with it, including the nature by which data integrity and security should be maintained as well as the need for intense documentation on any derived product from this platform.
- 2. The United States Congress passed the HITECH Act, drafted by the Department of Health and Human Services (HHS) around Meaningful Use (MU); that is, the proliferation and wide-spread adoption (through MU



policy) of EMRs into care environments. This policy created incentives for any healthcare technology innovation to be introduced into an integrated health information technology (HIT) environment, but especially through the EMR. Needless to say, the project had to pay attention to these newly but loosely defined policies that were beginning to take effect. The figure below depicts how the project supports both the current and future aspects of meaningful use as directed in federal policy.

	Stage 1	Stage 2	Stage 3
Diabetes Consort Features	(Structured Data)	(Information Sharing & follows the Patient)	(Quality Improvement & Population Health)
Control Center (Standards of Care)	Engages patient & family in quality measure reporting	Incorporates structured lab results	Improves quality, safety, efficiency
Patient Summary (Labs, & self-reported data)	Clinical Decision Support  Disease management  Medication management	Electronically transmits patient summary to provider	Decision Support
Logbook & Real-time Feedback (BG, medications, carbohydrates)	Not included in this stage	Not included in this stage	Self-Management Tools Improve quality, safety
Message Center (Trending & interpersonal messages)	Medication & management of disease		Improve efficiency

Figure 2. Mapping of Diabetes Consort Features with Meaningful Use Stages and Rules.

3. After the project had begun, WellDoc announced the outcomes from a large, randomized control trial (RCT) that was conducted under the auspices of the University of Maryland School of Epidemiology, Care First Blue Cross Blue Shield, Johnson and Johnson, and Sprint-Nextel. In this RCT, patients who had access to WellDoc's solution decreased their hemoglobin A1c by 1.9 points, compared with a 0.7 drop in the control



group, a very significant clinical and marketing outcome<sup>21</sup>. In addition, HCPs who had access to WellDoc's solution increased their prescribing behavior by over two-fold, breaking the common inertia in the movement of pharmacotherapy prevalent with most primary care physicians today. It is interesting to note that very similar results were obtained in an earlier RCT with WellDoc in 2008<sup>22</sup>. These combined findings caused our project team with the AF to "re-think" some of our objectives: if clinical outcomes had already been demonstrated, could there be an opportunity to observe and test some of the more operational aspects of the integration of MIT into EMRs, in addition to the clinical observations that would be collected?

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<sup>&</sup>lt;sup>21</sup> Quinn CC, Shardell MD, Terrin, ML, Barr EA, Ballew SH, Gruber-Baldini AL. A cluster randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011, Sep; 34: 1934-42.

<sup>&</sup>lt;sup>22</sup> Quinn CC, Clough SS, Minor JM, Lender D, Okafor MC, Gruber-Baldini A. WellDoc mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. Diabetes Technol Ther 2008;10:160–168.



## **Project Objectives**

With this broader context of the "need", we now provide a brief description of the project itself, and then proceed to catalog and examine our lessons learned.

The project is broadly segmented into three task areas:

- Task 1: Integrate the WellDoc Diabetes Consort® MIT system into GWMFA's Allscripts Enterprise EMR to create the Mobile Diabetes Management (MDM) solution for patients and facilitate enhanced data for providers.
- **Task 2:** Conduct a human factor (pilot) study to determine the usability of MDM by clinicians and patients using the MDM solution. The pilot would run concurrent to Task 3 a longer clinical trial.
- Task 3: Partner with GWMFA to conduct a clinical study to determine the solution's impacts on patient outcomes and diabetes management.
   MDM will be implemented at the GWMFA for patients with diabetes.

This white paper addresses lessons learned from Task 1 only. While these three tasks are depicted with a sense of linearity, what actually transpired during the course of Task 1 was quite complex, as depicted earlier in Figure 1. And, as we continue to explain, it is in the context of these complex factors that we have been able to glean many lessons learned from which the industry can benefit in future integration efforts of patient applications with EMRs. As we address Tasks 2 and 3 in the clinical study, we will observe and record additional lessons learned.

It is in light of these observations and opportunities that the project tackled a wider set of objectives and complexities, as it presented a rare opportunity to continue the momentum and velocity that MIT solutions were gaining in the industry. In the course of these modifications, there were several lessons learned that are valuable for the industry to note. We now introduce and explain the framework that we've



employed to take stock of these lessons learned, and will follow with an executive summary of these lessons, as well as a detailed view in the subsequent portions of this white paper.



## Organization of Lessons Learned

AIM: The Architecture for Integrated Mobility

To organize these lessons we have captured in integrating WellDoc's Diabetes Consort mHealth application platform into the Allscripts EMR, we invoke the Architecture for Integrated Mobility® (AIM®)<sup>23</sup>. AIM is a proprietary solution reference architecture authored and developed by Dr. Anand K. Iyer when he led the wireless strategy practice at PRTM Management Consultants. AIM was created as a means of defining the "layers" and best practices for integrating mobile solutions into in-theater distribution logistics management systems for the US Army G4. By applying AIM, we catalog our learning into similar and distinct "layers"; the lessons therein can then be used by various stakeholders to refine and improve future approaches to such leading-edge integrative efforts.

The AIM reference architecture is comprised of eight layers, the description of each provided below:

Layer	Description and Application to MIT
L1: Users	Includes the various stakeholders who use the system at
	different points in the service delivery life-cycle (e.g., from
	awareness through on-boarding, training, use, support,
	trouble management, upgrade and end of life (EOL)). This
	layer focuses on insights related to the value propositions
	and unique needs of each stakeholder as they interact with
	the integrated MIT solution.

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<sup>&</sup>lt;sup>23</sup> Iyer, Anand K. ,"Developing an Information-Enabled Architecture to Modernize In-Theater Distribution", United States Army G4 Report, September 30, 2005



L2: Application	Includes the actual features of the application as deployed.
	This layer details learnings related to the actual MIT feature
	set that is deployed and their desired attributes as well as
	shortcomings that should be noted.
L3: Environment	This layer addresses the physical, regulatory and security
	lessons learned during the course of MIT integration into
	an EMR setup.
L4: Device	This layer addresses lessons learned regarding the end-user
	devices (e.g., mobile Internet devices (MIDs), and their
	desirable attributes and shortcomings that must be taken
	into consideration.
L5: Network	This layer focuses on the aspects of the connectivity layer
Connectivity	that must be taken into account to ensure proper
	persistence, resilience, and availability to support the
	desired MIT integration.
L6: Services	As with any deployment, services excellence (user-facing)
	must be taken into consideration. This layer describes key
	lessons learned in this category.
L7: Core	At the heart of this project is the actual integration layer
Integration	between the MIT and the EMR. This layer captures lessons
	learned that address items such as data standards, data
	mapping, application integration, systems integration, and
	workflow integration.
L8: Operating	Because the integration of MIT into EMRs necessarily
Model	involves a heterogeneous set of players and development
	cultures in the value chain, there are a number of lessons
	learned around the collaborative operating model that we
	have attempted to capture.



## Summary of Lessons Learned

Below are the high level lessons learned that have percolated from each layer. The logic and rationale behind these summary lessons are further expanded and illuminated in the subsequent sections of this white paper, each of which "double clicks" on a unique layer in AIM.

- broad swath of actors with actions that each can take with the system in a manner that best fits their day-to-day life and workflow.
- Application: Many interrelated and mutually reinforcing feature sets are required to move the needle on patient outcomes, physician prescribing, practice behavior, and ultimately, the incurred economic costs. But these features should be designed in an open, interoperable fashion to accommodate the integration of many MITs into the same EMR environment.
- Environment: Precision is critical in the configuration of multiple operating environments for the integrated MIT-EMR system. Also, a security architecture that allows the secure and HIPAA-compliant sharing of personal health information (PHI) must be architected from the inside out.
- Device: The integration of MITs and EMRs must seamlessly accommodate multiple mobile internet devices, operating systems, UIs, physical characteristics (e.g., screen resolution), and secure over-the-air (OTA) provisioning such that revision control can be effectively managed.



- Network Connectivity: To accommodate the Radio Frequency (RF) connectivity constraints imposed by most hospitals and care centers, it is imperative to develop the MIT in a manner that works in multiple connectivity modalities such as "always connected", "periodically connected", and "sparsely connected." Additionally, contrary to the belief of many, the need for network resources (e.g., spectrum, bandwidth) is not a limiting factor for success due to the narrow-band nature of the data layer associated with many MITs.
- Services: Extensive awareness, education, and training are required to ensure full communication and endorsement of the value proposition to HCPs.
- Core Integration: It is necessary, but not sufficient alone, to declare that MIT-EMR integration will involve a standard such as HL7. It's imperative to go several layers deeper, to understand: 1) the mapping between different data fields; 2) how interpretation may vary between sources; 3) the rules behind data integration (e.g., which data source is the "source of truth"); and 4) the ongoing management, cleansing, and maintenance of these different data sources. Additionally, data integration without workflow or process integration will not achieve the desired objectives nor unlock the full potential of MIT-EMR integration.
- Operating Model: It is imperative to implement cross-enterprise, co-development best practices that structure: 1) governance; 2) a hybrid agile-waterfall product development methodology from requirements capture to test acceptance; 3) the cross-functional core team; and 4) change management best practices in order to achieve program objectives with the optimum levels of cycle-time, performance, cost, and quality.



The integration of MITs into EMRs must carefully map a broad swath of actors with actions that each can take with the system in a manner that best fits their day-to-day life and workflow.

Due to the heterogeneous nature of the "use cases" that are born from integrating MITs into EMRs, it is imperative to understand and validate a thorough set of actors and actions that each can take. Unlike the direct-to-consumer application market (e.g., apps that are available on iTunes, Google Play, etc. that are generally not FDA-cleared medical devices) where the principal actor is the patient, the introduction of the integrated EMR environment presents an expanded set of actors. These include, but are not limited to, the following:

- Patient
- Caregiver (for patient support)
- Educator or Trainer (during on-boarding and on-going support)
- Nurse
- Doctor
- Resident
- Study Coordinators
- Hospital IT and Billing Staff
- EMR Vendor
- MIT Vendor

Once this spectrum of actors has been identified, it's paramount to understand the actions that each can take. Actions include items such as:

- Identification of participating patients and healthcare providers
- Registration and training
- Medication validation
- Use of the MIT solution
- Care and support



Once the actors and actions are mapped, several questions must be addressed:

- 1. Common Definition of Actors: How is role equivalency achieved? For example, does a care manager's role as defined in the MIT solution match their role in the integrated EMR environment?
- 2. Trust in Data: Do healthcare providers in the integrated EMR environment trust the data that is being self-reported matches the data and insight provided by the MIT with the workflows of the user? Workflow analysis of the various uses of the data should be modeled to determine the set of MIT features to be of most use to that user. Given the number of possible workflows that could utilize the data provided by the MIT, it may be necessary to prioritize what user and which workflows will be supported first to get the best user acceptance and promote the most positive patient outcomes. Additionally, how should rules and standard operating procedures around the "trust and acceptance of data" be created? How should the person doing data entry or the author of the data be distinguished?
- 3. Workflow-Data Management: Today, the workflow for doctors is more schedule and procedure oriented, while the health care team is poorly organized to support chronic disease care. How should actions be configured to cause minimal changes in workflow for different types of HCPs, while incorporating the patient-centric care coordination that is being promoted through initiatives such as the Patient-Centered Medical Home (PCMH) and Accountable Care Organizations (ACO)?



Many interrelated and mutually reinforcing feature sets are required to move the needle on patient outcomes, physician prescribing, practice behavior, and ultimately, the incurred economic costs. But these features should be designed in an open, interoperable fashion to accommodate the integration of many MITs into the same EMR environment.

In order to move the needle on patient and physician behaviors, it's necessary for the MIT to contain the following features:

- Patient real-time coaching that provides feedback that's contextually and temporally relevant, and that's delivered in a manner that is "behaviorally-acceptable" to the patient
- Patient longitudinal feedback that's delivered via an expert system, and that analyzes data trends and patterns which could provide key insights into patient behaviors and corrective actions
- Clinical decision support that relies on evidence-based medicine and governing body best practices to utilize patient data and provide a meaningful set of "highlights" and "recommendations" to the HCP

It is in the context of the third feature that we offer the following observations:

- Prior to integration, it is imperative to capture dependencies from other MITs and the inherent features within the EMR. Which data fields will be duplicated, and which will be required as the trusted source by other applications? Without this analysis and definition, the consequences of MIT-EMR integration will outweigh its benefits.
- A key part of feature development is matching the data and insight provided by the MIT with the workflows of the user. Workflow analysis of the various uses of the data should be modeled to determine the set of MIT features to be of most use to that user. Given the number of possible workflows that could utilize the data provided by the MIT, it may be necessary to prioritize what user and workflows will be supported



first to get best user acceptance and promote the most positive patient outcomes.

- Medication validation and medication reconciliation workflows must be carefully planned. EMRs often contain outdated medication information, and in the case of insulin (single or Multiple Daily Injections (MDI)) patients, regimens can vary daily (e.g., sliding scale, insulin-to-carb ratio, etc.). Additionally, medication validation and reconciliation cannot be self-administered by the patient; a licensed HCP must perform this function. Modeling these workflows is crucial to ensuring accuracy in how medications are handled between the MIT and EMR.
- Data Display: It is imperative to understand what data needs to be presented, at what frequency, and with what modality. Different HCPs will require different manifestations of data presentation, and extra effort must be made to understand these requirements.
- The display of data supports different users' access to data that is easy to use, manipulate, and navigate. Understanding the different requirements around the view and use of data across the MIT and EMR systems is critical to supporting how data from the MIT is made available/updated in the EMR system. While drug databases are fairly standard, EMR and MIT systems may not use the same database and/or same version of a common drug database. A common terminology across disparate drug databases, e.g., RxNorm, can make interoperability of medication lists easier; however, it requires that both the MIT and EMR systems be able to map uniquely to the terminology.
- Most MIT solutions tend to be architected from the patient outward, while most EMRs are architected from the provider and workflow inwards. Therefore, MITs that are integrated into the EMR environment must be analyzed to ensure that workflows are aligned and avoid duplicate or even conflicting efforts/entries on the part of the patient and provider.



Precision is critical in the configuration of multiple operating environments for the integrated MIT-EMR system. Also, a security architecture that allows the secure and HIPAA-compliant sharing of personal health information (PHI) must be architected from the inside out.

The environment – that is, the physical and logical configuration of infrastructure, software, security mechanisms, and the like – is an area that is always assumed to be "covered." Yet it is in this domain that many issues were uncovered during the scoping, installation, provisioning, and acceptance activities.

#### Infrastructure

- Firewalls on both ends should be compatible. We experienced many difficulties in configuration due to the inherent differences between Cisco and Juniper solutions, as one example.
- Capacity, reliability, and availability of servers should be assessed to ensure that interfaces do not shut down due to the dynamic and variable volume of data traffic.

### Configuration and Management

- Staging and production environments should be identical in order to isolate and restrict trouble-shooting to application-related issues.
   In many cases, SSL certificates were not replicated in both environments, causing issues in the production environment.
- It is imperative to use trusted third-party certificates for authentication. In our case, a self-signed security certificate was installed instead of a third-party trusted certificate. When access to our application from AllScripts was attempted, our authentication mechanism did not trust the certificate and it subsequently rejected the request. Because of this, authentication failure exception was indicated and study coordinators could not enroll any patients into the MIT solution. Simply put, the self-signed certificate's purpose is



- to replicate a secured means of communication in local/development environments and should not be used in production environments.
- Setting up the production environment is a long-lead-time item and should be completed early enough to never become critical path.
- It is imperative to have dedicated, technically trained staff to manage infrastructure, with specific experience in configuring and managing virtual private network (VPN) tunnels.
- Security must be "built-in." In order to comply with PHI and HIPAA policy, it's imperative to adhere to proper encryption (e.g., NIST-certified AES-256) techniques on devices, on the link and on the servers, and standard token-based authentication that can then securely establish and manage a data connection between the MIT device and the EMR. The MIT solution should be an inherent secure application, therefore simplifying the Virtual Private Network (VPN) architecture between the cloud-side of the MIT solution and the EMR (vs. trying to extend the VPN to the mobile client side).



The integration of MITs and EMRs must seamlessly accommodate multiple mobile internet devices, operating systems, user interfaces, physical characteristics (e.g., screen resolution), and secure over-the-air (OTA) provisioning such that revision control can be effectively managed.

The proliferation of smart phones (e.g., Apple's iOS-driven iPhone and those that run on Google's Android OS, etc.) has driven a tremendous increase in the number of applications and data transacted over the cellular networks. It is well known that there are two fundamental architectures to leverage when implementing any mobile solution<sup>24</sup>: one which takes advantage of the native operating system capabilities (e.g., iOS, Android), and the other that implements web solutions (e.g., HTML5). The former is typically employed when user engagement is required, the latter when transaction efficiency is the goal. Needless to say, in the realm of mobile health, driving and sustaining patient engagement is critical, but this does not come without its implementation challenges.

- By necessity, multiple code bases must be maintained for each operating system. It is therefore valuable to apply common-domain logic-driven design when developing the MIT solution, such that the maximum amount of code (at the data layer, logic layer and user interface (UI) layers) is common across multiple operating systems.
- Within a given operating system, different mobile internet devices (MIDs) have different resolutions. To drive the best user-experience and to avoid "stretchy" or "compressed" images and text due to pixilation, it's helpful to re-factor each code build to ensure that the MIT is available in different screen resolutions to match the resolutions of the many devices available. This problem is particularly inherent to Android OS phones

http://www.forbes.com/sites/fredcavazza/2011/09/27/mobile-web-app-vs-native-app-its-complicated/ Accessed 11/9/2012.



- and Java (J2ME) phones, though it is lesser issue when it comes to iOS (since there are only two resolutions in this entire platform).
- The greater extent to which patients can use their own phone (and therefore have access to the MIT solution as well as their regular functions on the same device) represents an advantage. Extra effort will be required to ensure that the MIT solution is interoperable on many phone models.



In order to accommodate the Radio Frequency (RF) connectivity constraints imposed by most hospitals and care centers, it is imperative to develop the MIT in a manner that works in multiple connectivity modalities such as "always connected", "periodically connected", and "sparsely connected." Additionally, contrary to the belief of many, the need for network resources (e.g., spectrum, bandwidth) is not a limiting factor for success due to the narrow-band nature of the data layer associated with many MITs.

While the lessons learned in this section are less germane to the actual integration between the MIT and the EMR, we should make a few comments as it relates to the transport layer for a properly-engineered MIT-EMR solution. It is well established that wireless coverage in most hospitals and care facilities is poor, due to the nature of the construction of such facilities (lead-lined exam rooms, high volume of interior walls) and the fear of cellular interference with key medical equipment and diagnostic devices. Therefore, and in the absence of more sophisticated distributed antenna systems (DAS) or other in-building wireless systems<sup>25</sup>, MITs are best architected to operate in a hybrid client-cloud mode. That is, the MIT solution must perform the basic functions (e.g., patient coaching, patient feedback, out-of-bounds coaching, etc.) in both off- and on-line modes. Off-line operation adds complexity to how the application is coded, secured, and tested, but serves the higher-level purpose of ensuring persistence and continuity in the use of the MIT, regardless of Also, when the patient's device, which may integrate such the environment. emerging technologies as NFC (near-field communications, e.g., low-power, nonmedical interfering communications) is brought into the care facility, it can be placed in a "kiosk" mode that allows it to connect to the in-care facility EMR.

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<sup>&</sup>lt;sup>25</sup> http://www.ibwalliance.org/ Accessed 11/9/2012



Extensive awareness, education, and training are required to ensure full communication and endorsement of the value proposition to HCPs.

Currently, the implementation of EMRs – whether voluntary or in response to (and to remain compliant with) Meaningful Use legislation – is steadily growing. One of the main difficulties often cited is that workflow modifications are necessary when adopting such systems, and in the transition phase, the work load is nearly doubled (as both paper and electronic records are being generated and maintained). The value proposition of an integrated MIT-EMR solution must emphasize and communicate three benefits:

- First, the time to review a patient's chart with the MIT solution's data
  presented within the EMR environment is more organized and does
  not rely on the patient presenting incomplete, paper-based records or
  logbooks. Accuracy is increased and context for patient self-reported
  data is better established. Provided with a more robust picture of the
  patient's status over time, the effectiveness of a short office visit with a
  patient increases.
- Second, much of the "behind-the-scenes" work a doctor must do with a
  patient (e.g., "don't forget to bring you logbook, don't forget to bring
  your pill box", etc.) are not billable. These activities take valuable time
  and therefore there is productivity uplift for healthcare providers when
  the data they seek and need to optimize therapy decisions is available,
  formatted, structured, and actionable.
- Finally, such MIT-EMR integrated tools help healthcare providers do what they originally went into practice to do that is, to help their patients manage their chronic conditions by providing the longitudinal view of the disease progression, the actions of the patient over time, the efficacy of the plan of care between visits, and meaningful discussion points based on issues derived from patient self-reported data.



It is necessary, but not sufficient alone, to declare that MIT-EMR integration will involve a standard such as Health Level 7 (HL7). It's imperative to go several layers deeper, to understand: 1) the mapping between different data fields; 2) how interpretation may vary between sources; 3) the rules behind data integration (e.g., which data source is the "source of truth"); and 4) the on-going management, cleansing, and maintenance of these different data sources. Additionally, data integration without workflow or process integration will not achieve the desired objectives and unlock the full potential of MIT-EMR integration.

This layer in our lessons learned covers the actual integration activities, and addresses the following categories: Mapping of objects, standards, and workflow integration.

### **Mapping of Objects**

• It is important to ensure that the findings defined in either the MIT or EMR can be mapped to each other correctly. A blood glucose in the MIT refers to a finger stick value, whereas blood glucose in the EMR may be representative of a venipuncture value. The two systems require the use of a common terminology, with common coded values, in order to correctly map the clinical data each system collects to each other. Today, no EMR system tracks real-time patient self-reported data in a behavioral context and provides recommendations based on analysis of patient data with clinical data. Integration of self-reported and system generated data is a challenge in terms of display and interpretation of these different data sources.

#### **Standards**

 HL7 is a data interoperability standard that allows two or more systems to share data. In order for an EMR and MIT to share data, both systems must adhere to a set of rules that define a common data format and



behavior. While EMRs have a measure of commonality, for the most part adherence to these standards is a new domain space for MITs. Additionally, no two EMRs adhere to these standards in the same way and any MIT would need to be customized for each individual EMR for a data exchange to occur.

### **Workflow Integration**

• It is important to evaluate not only the new capability that arises from MIT-EMR integration, but perhaps and more importantly the effect on existing capability. For example, our MIT's patient registration process had a workflow and data capture sequence quite different than that adopted by nurses using the EMR. The same differences manifested themselves at the opposite end, in the periodic patient visits, where the MIT's patient visit summary is used differently than patient reports are used in the EMR by HCPs.



It is imperative to implement cross-enterprise, co-development best practices that structure: 1) governance; 2) a hybrid agile-waterfall development methodology from requirements capture to test acceptance; 3) the cross-functional core-team; and 4) change management best practices in order to achieve program objectives with the optimum levels of cycle-time performance, cost, and quality.

This layer in our lessons learned addresses the operating and business model aspects of the project, and includes discussion of industry observations, crossenterprise collaboration, and open innovation.

#### **Industry observations**

- Today, the MIT world does not understand the EMR world, and the
  reverse statement holds true as well. As more and more MITs are
  integrated into EMRs, the concept of "integration in a box" will begin to
  manifest, whereby all layers of integration have proven recipes that meet
  the outcomes, cost, quality, and cycle time objectives of the program
- EMR data may be converted into "information, knowledge, and action" via decision support, workflow engines, and business intelligence. However, the current data is interpreted by an HCP and that process of value extraction from the data happens with the HCP. By allowing MITs to integrate into EMRs, the amount of data available for bi-directional messaging increases, and so does the value of the ensuing information, knowledge, and actions that can be imparted to the patient and to the provider. The challenge then is how to incorporate patient self-reported data with EMR data and to deliver recommendations that are evidence-based and standards linked. Additionally, interfacing with lab and pharmacy data gives us the ability to better tailor recommendations to the provider and to coach the patient in daily self-management.
- Cross-enterprise collaboration and open innovation



- Integration of two emerging and nascent platforms is always more complex than it is made out to be!
- Cross-enterprise collaboration should include multiple elements such as a cross-functional steering committee (which assigns resources, resolves issues, and who is accountable for success), a cross-functional core team (which is responsible for executing the project successfully), visibility into program success, obstacles, and corrective measures via a program scorecard, as well as frequent and structured cross-enterprise communication such that short-term successes can be shared and obstacles quickly removed
- Resourcing is complex, and must include provisions for backup resources that can "step in" when needed.
- A calendar of events should be published, and during intense project periods (e.g., requirements sign-off, testing, and acceptance, etc.) the frequency of calendar updates and communications should increase.



#### Conclusion

As we have discussed in this white paper, there are many lessons to be gleaned from Task 1 of this market-leading initiative between the United States Air Force, WellDoc, The George Washington University Medical Faculty Associates, and EHRI. We anticipate that as more patients and providers are trained, and as the clinical trial continues, we will discover many more "nuggets" in the categories of the AIM framework. The clinical trial will provide additional learning about how the interfacing of patient self-reported data and clinical data can work to deliver both real-time coaching to patients and clinical decision support to providers – and how that will impact diabetes care metrics. We believe that as MIT and EMR solutions mature, standard configurations and "recipes" for different levels of integration (e.g., data integration only, systems and application integration, workflow integration, etc.) will be developed. Finally, and for now, we believe this summary of initial lessons learned will help create models for the industry to leverage in future innovations.

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### Appendix B: Journal Publication on Lessons Learned



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### Appendix C: April 18, 2013 WellDoc Presentation to Air Force



Click on icon to view and/or print presentation



### Appendix D: June 25, 2013 WellDoc Presentation to Air Force



Click on icon to view and/or print presentation